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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,326	11/28/2000	Keith A. Webster	10989-004-999	5537
7	7590 08/05/2002			
Pennie & Edmonds LLP 1155 Avenue of the Americas New York, NY 10036-2711			EXAMINER	
			PARAS JR, PETER	
			ART UNIT	PAPER NUMBER
			1632	17.
			DATE MAILED: 08/05/2002	17)

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/723,326	WEBSTER, KEITH A.			
Office Action Summary	Examiner	Art Unit			
	Peter Paras	1632			
Th MAILING DATE of this communication appears on the cover she it with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	mely filed ys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133).			
1) Responsive to communication(s) filed on					
	— · is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims					
4)⊠ Claim(s) <u>1-41</u> is/are pending in the application					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) <u>1-41</u> are subject to restriction and/or e	election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the	e drawing(s) be held in abeyance. S	See 37 CFR 1.85(a).			
11) The proposed drawing correction filed on	_is: a) ☐ approved b) ☐ disappro	oved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:					
1. Certified copies of the priority documents	s have been received.				
2. Certified copies of the priority documents	s have been received in Applicat	tion No			
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)		ry (PTO-413) Paper No(s) Patent Application (PTO-152)			



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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-27 and 30, drawn to an expression vector and a process of making the same vector, classified in class 435, subclass 320.1.
- Claims 28-29, drawn to a genetically engineered cell in vitro, classified in class 435, subclass 325.
- III. Claims 28-29, drawn to a genetically engineered non-human organism, classified in class 800, subclass 13.
- IV. Claim 31, drawn to a process of using an expression vector, classified in classes 435 and 435, subclasses 455 and 70.1.
- V. Claims 32-41, drawn to an isolated polynucleotide, classified in classes536 and 536, subclasses 23.1 and 24.1.

Inventions I-IV are unrelated each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The products of Groups I-IV can be used for different purposes, in different methods that require different reagents and technical considerations. For example, the vector of Group I can be used to transform a



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host cell in vivo, the genetically engineered cell in vitro of Group II can be used to produce a protein, the genetically engineered non-human organism of Group III can be a model for disease, and the polynucleotide of Group IV can be used as a probe in a hybridization assay *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product. It would appear that claim 30 as written encompasses transformation of a cell. Other inducible vector systems, are known in the art, and can be used to transform a cell. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II, III, V and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

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808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of inventions II, III, and V can be used in materially different methods from the method of invention IV while the method of invention IV can be practiced with reagents, which have different chemical structures from the products of Inventions II, III, and V and require different technical considerations. The genetically engineered cell *in vitro* of Group II can be used for detecting gene expression, the genetically engineered non-human organism of Group III can be used as a model of disease for screening potentially therapeutic compounds, the polynucleotide of Group V can be used as a probe in a hybridization assay *in vitro*, while the method of Group IV can be used to produce a protein *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).



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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

Pete Parage Art Unit 1632

Peter Paras, Jr.

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